

Honorable Donna Shalala
Secretary of Health and Human Svcs
Room 615F
200 Independence Ave. SW
Washington DC 20201

17Oct2000

Dear Mrs. Shalala:

The Food and Drug Administration is in the process of proposing changes to the way hearing aids are sold that could put me out of business and impede access to hearing care services for millions of our nation's hearing impaired and seniors.

I am a Board Certified, State Licensed, Hearing Instrument Specialist. For over 24 years, I have provided quality health care services to thousands of our state's hearing impaired. Presently all three members of the hearing health care delivery team, (Hearing Instrument Specialist, Audiologist, and Physicians) are recognized as qualified entry points into the hearing health care delivery system. The rule FDA is advocating would allow audiologist without any justification, to instill themselves as the sole entry point into hearing healthcare by allowing states to require expensive and **non essential test** that only audiologist are qualified to perform.

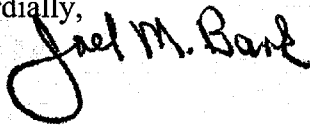
Allowing audiologist an exclusive role in the hearing aid delivery system, without unqualified medical data evidencing that such a role is necessary for public health reasons, would severely undermine public health and safety and would increase cost to the hearing impaired.

The medical community, specifically the American Academy of Otolaryngologists (Ear, Nose and Throat) **opposes** this FDA proposal.

Please contact the Secretary of Health and urge that this FDA proposed hearing aid rule be withdrawn.

I look forward to your response.

Cordially,



Joel M. Bank, M.A., A.C.A., BC-HIS

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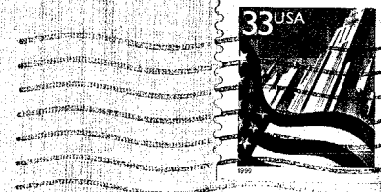
Joel M. Bank, M.A., A.C.A., BC-HIS
Master's Degree in Audiology
Board Certified Hearing Instrument Specialist
Audioprosthesologist
Better Hearing Through Professional Care

C 4813

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1510 3rd Avenue
Tuscaloosa, AL 35401



Honorable Donna Shelala
Secretary of Health &
Human Services
Room 615F
2009 Ave. S.W.

